FEB 1 2 2014

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Ningbo Lishunda Electronics Co., Ltd.
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Yuyao, Zhejiang Province, China
Tel: 86- 574-62240910
Submitter's FDA Registration Number: N/A

US Agent and Contact Person

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Date of Summary: January 3, 2014

Device Name:	
Proprietary Name:	"OWL Contact Lens Cases" and "DOG Contact Lens Case" (or other clients private labeling)
Common Name:	Contact Lens Case
Classification Name:	Soft (Hydrophilic) Contact Lens Care Products
Device Classification:	2
Regulation Number:	21 CFR 886.5928
Panel: General	Ophthalmic
Product Code:	LRX

Predicate Device Information:

(1) K120904, "The Polaris Dial-a-Date Contact Lens Case", manufactured by "Reliance Design & Manufacture Corp." in Tainan, Taiwan

Device description:

The "OWL Contact Lens Case" and "DOG Contact Lens Case" are medical device for the storage of soft (hydrophilic) and rigid gas permeable contact lenses. The applicant device of Contact Lens Case consists of two parts: case body and case lid. The case body

is based with adjoining dual wells for the containment of fluid, and the two lids are designed for screwing.

"OWL Contact Lens Case" has a well diameter of 27 mm, well capacity of 5.5 mL, and overall dimension of 71 x 38.5 x 17 mm (length x width x height). The case body is in blue color and case lids are in white and black colors. Inside of the lid has only white color and has no black color.

"DOG Contact Lens Case" has a well diameter of 25 mm, well capacity of 4.8 mL, and dimension of 69.5 x 38 x 14 mm (length x width x height). The case body is in blue color and case lids are in blue, black and white color. Inside of the lid has only blue color and has no white and black color.

Contact lenses can be fully immersed into the well, and the well from both models accommodates all lenses currently being sold in the market. The bottom of each well is marked with L (left) or R (right).

The applicant device of Contact Lens Case is made of Acrylonitrile - butadiene - styrene copolymer (ABS).

Intended Use:

The "OWL Contact Lens Case" and "DOG Contact Lens Cases" in this application are a device intended for the storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for use during heat disinfection.

Comparison to Predicate Devices

The "OWL Contact Lens Case" and "DOG Contact Lens Cases" are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K120904, "The Polaris Dial-a-Date Contact Lens Case", manufactured by "Reliance Design & Manufacture Corp." in Tainan, Taiwan

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device (K120904)
Indication for Use	The "OWL Contact Lens Case" and "DOG Contact Lens Cases" in this application are a device intended for the storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for use during heat disinfection.	The Polaris Dial-a-Date Contact Lens Case is intended for the storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for use during heat disinfection.
Basic Design	Two adjoining wells with screw down lids	Same
Materials	Acrylonitrile-Butadiene-Styrene Copolymer	Polypropylene and other polymer mixture
Size	OWL: 71 x 38.5 x 17 mm (length x width x height) DOG: 69.5 x 38 x 14 mm (length x width x height)	68 x 32 x 21.5 mm (length x width x height)
Volume	5.5 mL (OWL) and 4.8 (DOG)	4.4 mL
Colors	Three outer lid colors (white, black and blue)	Four outer lid colors

Our device of OWL and DOG Contact Lens Cases are the same with the predicate device in indications for use and basic design, similar to predicate devices in geometry and dimension. Our device and the predicate device have some minor differences in material and color, which will be discussed below.

The following table shows similarities and differences of the performance between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K120904)
Cytotoxicity (ISO 10993-5)	No cytotoxicity	No cytotoxicity
Eye Irritation (ISO 10993-10)	No Eye irritation	No Eye irritation
Systematic Toxicity (ISO 10993-11)	No systematic toxicity	No systematic toxicity
Leakage Test	No leakage	No leakage

Our device and the predicate device differ in the following three areas

(1) Our device is made from Acrylonitrile-Butadiene-Styrene Copolymer and has two colors on the outer lid, while the predicate device is made from polypropylene (95%) and other unspecified polymer mixtures (5%).

This difference does not affect the effectiveness and safety of our devices. Our device has been tested for cytotoxicity, eye irritation, and systemic toxicity. All results show that the material is not cytotoxic, causes no ocular irritation, and has no systemtic toxicity.

(2) Our device has three colors on the outer lid, while the predicate device has four colors on the outer lid.

This difference does not affect the effectiveness and safety of our devices. The color additives we use are medical grade. Additionally, the device (with the color additives) has been tested for biocompatibility, and results show that the material is not cytotoxic, causes no sensitization and irritation, and has no systematic toxicity.

(3) Other minor differences that do not affect the safety and performance: the predicate device has a moveable part on the top lid to set a reminder while our device has a plain top.

A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Leakage Testing: Production units of both OWL Contact Lens Cases and DOG Contact Lens Cases have undergone leakage testing. 128 combinations of different tops and bottoms were filled to 2/3 with liquid. Each set was turned upside down for 15 minutes and the tests were repeated 3 times.

None of the tested lens cases showed any leakage and all of the Leakage Tests passed successfully.

A brief discussion of the clinical tests submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is typically not needed for contact lens case.

Substantial Equivalent Conclusions

Based on the comparison of intended use, design, materials, and performance, both OWL Contact Lens Cases and DOG Contact Lens Cases are substantial equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

February 12, 2014

Ningbo Lishunda Electronics Co. Ltd.
% Mr. Charles Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534

Re: K130930
Trade/Device Name: OWL Contact Lens Case
DOG Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: January 8, 2014
Received: January 9, 2014

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K130930

Device Name
OWL Contact Lens Case; DOG Contact Lens Case

Indications for Use *(Describe)*

The "OWL Contact Lens Case" and "DOG Contact Lens Cases" are a device intended for the storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for use during heat disinfection.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Leonid Livshitz -S
2014.02.10 17:13:53 -05'00'

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